APPENDIX II: Clean Copy of Claims upon Entry of Amendments



- 1. (Twice amended) A drug delivery composition for delivering a drug to the colonic region comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum.
- 2. A drug delivery composition according to claim 1 wherein the coating comprises a material which dissolves at a pH of 5 or above.
- 3. A drug delivery composition according to claim 1 wherein the coating comprises a material which is redox-sensitive.
- 4. A drug delivery composition according to claim 3 wherein the coating comprises an azopolymer or a disulphide polymer.
- 5. A drug delivery composition according to claim 1 wherein the coating comprises a material which is degraded by enzymes or bacteria present in the colon.
- 6. A drug delivery composition according to claim 2 wherein the coating comprises methylmethacrylate or a copolymer of methacrylic acid and methyl methacrylate.
- 7. A drug delivery composition according to claim 2 wherein the coating comprises a cellulose ester.
- 8. (Amended) A drug delivery composition according to claim 1 wherein the coating has a thickness in the range of 80 μ m to 300 μ m.
- 9. (Amended) A drug delivery according to claim 1 wherein the drug is one which acts locally in the colon.
- 10. (Amended) A drug delivery composition according to claim 1 wherein the drug is for systemic delivery and systemic action.

AMENDMENT AND RESPONSE TO OFFICE ACTION

- 11. (Amended) A drug delivery composition according to claim 1 wherein the drug is a vaccine for delivery to the lymphoid tissue of the colon.
- 12. A method of delivering a drug to the colonic region of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum.
- 13. (Twice amended) A method of delivering a vaccine to the lymphoid tissue present in the colon of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the vaccine and wherein the starch capsule is provided with a coating such that the vaccine is predominantly released from the capsule in the colon and/or terminal ileum.

